



DT06 Rec'd PCT/PTO 06 SEP 2002

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Petitioner's Docket No. U 013943-5

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

OR

In re application of: **AMARJIT SINGH**, et al.

Serial No.: 10/089,020

Group No.: --

Filed: MARCH 25, 2002

Examiner.: --

For: CONTROLLED RELEASE COMPOSITIONS COMPRISING NIMESULIDE

Assistant Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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- ☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

37 C.F.R. 1.8(a)

37 C.F.R. 1.10\*

- ☒ with sufficient postage as first class mail.

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- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: August 30, 2002

Signature

JANET I. CORD

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. 1.98(b):

- (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.
- (2) Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.
- (3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.
- (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.
- (5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

**WARNING:** No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).

**NOTE:** The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

**NOTE:** "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

**NOTE:** "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

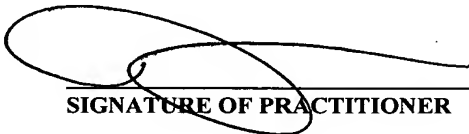
**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

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**SIGNATURE OF PRACTITIONER**

**JANET I. CORD**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: AMARJIT SINGH, et al.

Serial No.: 10/089,020

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Attorney Docket No.: U 013943-5

Assistant Commissioner for Patents  
Washington, D.C. 20231


Sirs:

INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached English-language version of an International-type Search Report from a foreign office in respect of counterpart International Application No. PCT/IN00/00094 that indicates the degree of relevance found by the foreign office. The Search Reports make consideration of any non-English art required. MPEP 609.

Form PTO-1449 is also attached with reference copies.

Respectfully submitted,

  
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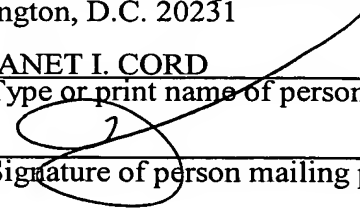
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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231

JANET I. CORD  
(Type or print name of person mailing paper)

Date: August 30, 2002

  
(Signature of person mailing paper)

<b>FORM PTO-1449</b> <b>U. S DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b>	<b>SERIAL NO.</b>
	<b>U 013943-5</b>	<b>10/089,020</b>
	<b>APPLICANT</b>	
	<b>Amarjit SINGH, et al.</b>	
	<b>FILING DATE</b>	<b>GROUP</b>

REFERENCE DESIGNATION										U.S. PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER								DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA		4	6	6	6	9	2	8	5/1987	Young et al.	514	350	
	AB													
	AC													
	AD													
	AE													
	AF													
	AG													
	AH													
	AI													
	AJ													
	AK													

FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
														YES	NO
	AL		2	1	2	9	0	1	0	5/1999	ES				X
	AM		1	0	0	5	8	6	5	6/2000	EP			X	
	AN														
	AO														
	AP														

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)													
	AR	Nagoji, K.E.V, et al. "Release Studies of Nimesulide from Ethyl Cellulose and Ethyl Cellulose and Hydroxy Propyl Methyl Cellulose Matrices" <i>Indian J. of Pharmaceutical Sciences</i> , p. 482-484, (2000)											
	AS	Manna, A., et al. "Design and Evaluation of An Oral Controlled Release Microparticulate Drug ...Analysis" <i>J. of Scientific &amp; Industrial Research</i> , Vol. 58, p. 717-722, (1999)											
	AT	Derwent Abstract: Guo, S., et al. "Preparation and in vitro release characterization...tablets"											
		Accession number 1628, XP-002148832 (2000)											

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.